UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,212	10/30/2003	David R. Hennings	NSL-501	2780

34313 7590 02/22/2010

ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
02/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 01312010

Application Number: 10/699,212
Filing Date: October 30, 2003
Appellant(s): Hennings, David R. et al

James W. Geriak
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 22, 2009.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of claims is as follows:

This Appeal involves claims 1-17, 19-35, and 37-46.

Claims 18, 24, and 36 are cancelled.

(4) Status of Amendments After Final

No amendments after final have been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Listing of Evidence Relied Upon

The following is a listing of the prior art of evidence (e.g. patents, publications Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number (Title)	Name	Date
4,854,320	Dew et al	August 8, 1989
5,196,004	Sinofsky	Mach 23, 1993
5,207,672	Roth et al	May 4, 1993
6,258,084	Goldman et al	July 10, 2001
WO 92/17243	Conn et al	October 15, 1992
WO 93/15664	Makower et al	August 19, 1993

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 6, 7, 25-38, 40, 41, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al. Goldman et al ('084) teach a method as claimed, including the use of tumescent anesthesia (see Abstract,

second through fourth sentences and column 4, lines 43-60); heating the vessel wall to cause it to assume compressed dimensions, i.e. shrink (see Abstract, fifth and sixth sentences); moving the device in the vein to treat a larger segment thereof (Abstract, seventh sentence); and providing temperature sensors at the site (Abstract, last sentence); in the method of Goldman, the vein may be either partially or completely collapsed (see column 2, lines 41-65); this is achieved by applying sufficient thermal energy to shrink the tissue (see column 3, lines 52-56); and also involves removing a significant amount of blood from the area (column 3, lines 61-67); and that a laser may be used to provide the heating energy (see column 7, lines 53-59), but do not specify a wavelength. Sinofsky teaches the notorious nature of the high absorption of infrared wavelengths in the art (see column 4, lines 47-65). Dew et al teach the desirability of using 1.32 micron radiation to treat tissue (see column 5, lines 41-65). It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the method of Goldman et al ('084), since Goldman et al ('084) teach no particular wavelength, and since the wavelength of Dew can destroy (denature) the proteins, but allow near normal tissue to take its place (see Dew et al column 11, lines 37-44), and since this wavelength is highly absorbed by tissue and water, as taught by Sinofsky, or alternatively, to employ the venous treatment method of Goldman et al ('084) in the method of Dew et al, since Dew et al teach the repair of vascular tissue as one of the advantageous uses of their wavelength (see column 5, line 50-65, particularly lines 54-59), thus producing a method such as claimed.

Claims 3-5, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Roth et al. Roth et al teach employing pull back rate as claimed,

noting that the desired rate is dependent on the laser energy (see column 15, lines24-50). It would have been obvious to the artisan of ordinary skill to employ a pull back as claimed, since these are known in the art and provide no unexpected result and to initiate pulling prior to energy application, since the problem of tissue adhesion is notorious in the art official notice of which is herby taken, thus producing a method such as claimed.

Claims 8 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Conn et al. Conn et al teach a diffusing tip as claimed. It would have been obvious to the artisan of ordinary skill to employ a tip as taught by Conn et al, since this would provide a uniform distribution of light and would prevent over or under treatment of tissue different areas of tissue (see page 2, first full paragraph) around the circumference of the vessel, thus producing a method such as claimed.

Claim 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7 and 25 above, and further in view of Makower et al. Makower et al teach controlling the heating of tissue using infrared sensing (see the paragraph spanning pages 15 and 16). It would have been obvious to the artisan of ordinary skill to employ the temperature sensor of Makower et al in the method of Goldman et al ('084) since these are equivalents, as taught by Makower et al, thus producing a method such as claimed.

Claim 14-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Roth et al and Dew et al. Makower et al teach a device as claimed (see page 13, second full paragraph for the fiber and introducer; page 20, first full

paragraph for the means for administering anesthesia; and the thermal sensor is disclosed at the paragraph spanning pages 15 and 16, as above) except the particular laser wavelength and the pull back mechanism. Dew et al teach a wavelength as claimed for treating tissue. Roth et al teach a pull back mechanism providing the claimed rate. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the device of Makower et al, since Makower et al teach the use of an Nd:YAG laser, which necessarily produces this radiation, as taught by Dew et al and to employ the pull back mechanism of Roth et al, since this enables uniform treatment along the surface, as taught by Roth et al, thus producing a device such as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Dew et al and Roth as applied to claims 14-17 and 20-23 above, and further in view of Conn et al. Conn et al teach a diffusing tip on an introducer for a fiber (see figure 5 and the paragraph spanning pages 14 and 15). It would have been obvious to the artisan of ordinary skill to include the diffuser of Conn et al in the device of Makower et al, since this reduces problems due to breakage, as taught by Conn et al, thus producing a device such as claimed.

(10) Response to Argument

Preface

Appellants have three main points of argument:

a) Only the preferred embodiment of using RF energy to treat the varicose vein is enabled, while the secondary embodiment of using laser energy to provide the ligation of the vein is not enabled;

b) The remaining references with which Goldman et al is combined do not teach the treatment of varicose veins; and

c) Appellants feel the examiner has refused to consider the evidence submitted by appellants to establish non-obviousness of the claimed invention.

a) Goldman et al is enabled for laser application

Firstly, appellant argues that the 'Goldman is directed almost entirely to RF heating of varicose veins and contains only one throw-away sentence which mentions lasers at column 7, lines 53-59 and which says that "other forms of energy such as microwaves, ultrasound, direct current, unrelated (sic, circulating) heated fluid, radient light, and lasers can be used…". This single mention of lasers in Goldman is non-enabling and occurs only in the context of a listing of several possible alternatives to the use o (sic, of) RF energy, none of which are otherwise mentioned or enabled." (see the instant Brief, page 12, last full paragraph, second and third sentences). In support of this assertion, appellant has pointed to several pieces of case law, the first being *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 85 USPQ2d 1826 (Fed. Cir. 2008), this relates to the substitution of the image of a user in place of one of the characters in a video game or movie, this substitution is done by a device known as an "intercept adapter interface system" (IAIS) and the patent was found invalid with regard to the substitution of the user into a movie, despite the specific mention thereof in the disclosure (wherein there was only one such reference in the patent specification, and which included no details of the implementation thereof. However, this was because:

> "The district court found that Defendants' experts demonstrated that none of the identified analysis techniques for selecting, analyzing, or identifying character functions or intercepting character signals in video games would work for movies. Sitrick, slip op. at 58. The district court determined that:

> Movies do not have easily separable character functions, as video games do, and the patent does not explain how the IAIS either selects the character functions to be substituted for a user image or intercepts signals in order to effectuate that substitution.
>
> While in video games character functions are separately retrieved by discrete address signals, and the motion of each is controlled by discrete control signals, character images in pre-existing movies and animations are inseparable from other surrounding images. Pre-existing movies do not employ discrete address and control signals, or any other means for requesting separate image segments to be assembled into the character or the overall image that appear within each frame of the presentation. Rather, as Defendants' expert, Dr. Phillips, explains:
>
> Video signals representing pre-existing movies and animation are either digital or analog representations of a series of frames, wherein each frame comprises pixel or scanline information of the overall image in the frame. In contrast to a video game, with a dynamically created scenario, motion in a movie is provided by slightly varying the image of the character in each frame such that the continuous display of the frames creates the illusion of motion … .
>
> (Tiu Decl., Ex. L at 346.) The patent never discusses how a character function or predefined image can be identified and separately carved out of a frame."
>
> See *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 85 USPQ2d 1826, 1829 (Fed. Cir. 2008).

Thus the issue in *Sitrick* was the inability to use the same principles to implement the movie embodiment, which was not explained, as were used in the video game embodiment, which was fully explained. However, this is not the case here. Once again, the facts in the case law proffered by appellant do not coincide with the facts in the instant application. In the instant application, the application of various forms of energy, including lasers to blood vessels was known and understood by one of ordinary skill in the art, as evidenced by the disclosures of Dew et al and Sinofsky. Thus the decision in *Sitrick* is not applicable to the instant facts.

Next appellant points to *Automotive Technologies International Inc. v. BMW of North America Inc.* 501 F.3d 1274, 1285, 84 USPQ2d 1108 (Fed Cir 2007). Here it was decided that although the embodiment of mechanical side impact sensors was enabled, the embodiment drawn to electronic side impact was not, since

> "in view of fact that side impact sensing was new field when application was filed, and that there were no electronic sensors in existence that would detect side impact crashes, it was especially important for specification to discuss how electronic sensor would operate and to provide details of its construction"

See *Automotive Technologies International Inc. v. BMW of North America Inc.* 501 F.3d 1274, 1285, 84 USPQ2d 1108 (Fed Cir 2007). Here, at the time of filing of vascular treatment with lasers was not a new field, again as demonstrated by Dew et al and Sinofsky. Further, the use of lasers to treat varicose veins was also known at the time of filing of the instant application, as evidenced by the eleventh reference cited in the bibliography of the Min et al article that appellant has attached to the instant Brief as part of Appendix 2: "Boné C. Tratamiento endoluminal de las varices con laser de diodo: estudio preliminary. Rev. Patol Vasc. 1999; 5:35-46" (varices (plural of varix) are defined as "An enlarged or tortuous vein, artery, or lymphatic vessel"; while varicose is defined as "Relating to, affected with, or characterized by varices or varicosis; both from Stedman's Medical Dictionary, 26th Edition). Thus clearly the use of lasers to treat varicose veins was known at the time of the invention of Goldman et al ('084) and thus the facts of *Automotive Technologies* are also not applicable to the instant facts.

Finally, appellant resorts to an unpublished opinion, Medtronic Navigation v. Brainlab 222 Fed. Appx. 952 (Fed Cir 2007), wherein the patent in suit mentioned that an "optical system can be used as an alternative to the acoustic system described earlier" (see the instant Brief, page 13, last sentence), while the examiner has been unable to secure the text of this case, the immediately preceding sentence in the Brief states, in pertinent part "the patent was directed to an acoustic or ultrasound range finding system". Acoustic and ultrasonic range finding systems are based on echolocation: the measurement of the transit time of a sound wave from the emitter

to the object and back to a sensor. The speed of sound being about 330 meters per second, that means to measure a distance of 1 millimeter would require a temporal resolution of about 3 microseconds, which is not beyond the reach of current technologies, since microprocessors running at 1 Gigahertz can measure time in nanosecond increments. However, to construct such a system using light as the radiation the transit time of which is measured is an entirely different proposition, as the speed of light is 3×10^8 meters per second. This would require a temporal resolution of greater than 3 picoseconds (3×10^{-12} seconds), which is beyond the capability of current microprocessors, which to the examiner's knowledge even today do not have clock speeds of greater then 1 Terrahertz, le6t alone prior to 2007, when that patent in question litigated. Thus again, the fact pattern of the case law appellant relies on is not consonant with that of the instant application.

In conclusion, the disclosure and claims of Goldman et al ('084) do not "preempt the future before it has arrived", but encompass the state of the art as it existed at the time of filing of the application form which Goldman et al ('084) evolved

Then appellant makes the assertion that the examiner has attempted to "sidestep the Goldman Declaration". The examiner has done no such thing. The bases for this assert are set forth as:

1) the examiner's noting that claim 31 does not require tumescent anesthesia, appellant characterize this statement as "totally irrelevant", however, as paragraph 6 of the Goldman Declaration expressly states that this is the work upon which the patent was based, this fact can hardly be characterized as "totally irrelevant".

2) the examiner's noting that in the Goldman Declaration, Declarant uses the pronoun "we" without providing any antecedent therefor, calling into question whom this pronoun is supposed to encompass.

3) the examiner's noting that the inventor's of Goldman et al ('084) signed an oath that they had read and understood the application and claims filed. These arguments are set forth in the Final Rejection mailed March 13, 2009 and reproduced herein:

> this statement appears to be at odds with Declarant's signature on the Declaration of Goldman et al ('084), which avers that Declarant has read and understood the specification thereof, including the claims, which specification included the reference to the use of lasers, and which claims were broad enough to encompass such use, by virtue of merely reciting an energy source, rather than the use of RF per se. Thus, weighing Declarant's statement, wherein Declarant holds a vested interest in the issuance of the instant application, against the evidence afforded by a signed declaration in a U. S. Patent, with its attendant presumption of validity (which includes a presumption of operability), the examiner is not persuaded by Declarant's current stance, that the subject matter of the claims of Goldman et al ('084) is inoperable.

Now appellant asserts that this is a "house-of-cards" argument, based on the fact that none of the original claims recite a laser (appellant purports to have included a copy of the original claims, however, the examiner has been unable to locate these in the file, and has thus included the original claims filed in U.S. Patent Application No. 09/267,127, which matured into Goldman et al ('084) in Appendix). However, the salient point is not so much that none of the original or issued claims recite a laser, but that all the claims, original and issued recite only an "energy application device", none of the claims reciting either a laser or an RF source. Issued claim 1 of Goldman et al ('084) is exemplary:

> "1. A method of applying **energy** to a hollow anatomical structure from within the hollow portion od the structure, the method comprising the steps of:
> introducing a catheter having a working end with an **energy** application device at the working end into the hollow anatomical structure;

> positioning a working end of the catheter proximate a treatment site within the hollow anatomical structure;
> injecting a tumescent fluid solution into selected tissue which is in contact with the treatment site to cause the tissue to become tumescent and compress the hollow anatomical structure at the treatment site to a compressed size; and
> applying **energy** to the compressed hollow anatomical structure at the treatment site via the **energy** application device until the hollow anatomical structure durably assumes a smaller size."(emphasis added)

In order to construe the meaning of the term "energy" in this claim, it is necessary to look to the disclosure of the patent. In doing so, we find the term "energy" defined column 7, lines 53-59:

> "although the invention will be described as using RF energy from the electrode, it is to be understood that other forms of energy such as microwaves, ultrasound, direct current, circulating heated fluid, radiant light and lasers can be used, and that the thermal energy generated from a resistive coil or a curie point element may be used as well."

Thus clearly, the claims as they were originally submitted and as issued undeniably encompass the use of, among other things, lasers. This is a fact that was averred to be read and understood by the signatories of the oath submitted with U.S. Patent Application No. 09/267,127. The lack of specific recitation of the use of lasers as the energy source is immaterial to the fact that the broadly written claims encompass the use of lasers. This is hardly a "house-of-cards argument" as characterized by appellant. The fact that other energy sources were intended to be encompassed by the claims is further emphasized by claim 13:

> "13. The method of claim 1 wherein the step of applying **energy** to the compressed anatomical structure at the treatment site comprises applying **electrical energy** to the inner wall of the treatment site with an electrode, the electrode being in apposition with the inner wall."(emphasis added)

If the "energy" of claim 1 were to be construed as only encompassing RF, there would be no need to recite that the energy is electrical energy in claim 13. Lastly it is noted that the noting

of the breadth oif the originally filed and the issued claims by the examiner is not raised in relation to the issue of enablement per se, but to underscore that the inventors of U.S. Patent Application No. 09/267,127 were aware at the time of filing and the time of issuance of the Goldman et al ('084) patent aware of the breadth of these claims. It is on this basis that the examiner arrived at the conclusion set forth on page 7 of the Final Rejection mailed March 13, 2009:

> "Thus, weighing Declarant's statement, wherein Declarant holds a vested interest in the issuance of the instant application, against the evidence afforded by a signed declaration in a U. S. Patent, with its attendant presumption of validity (which includes a presumption of operability), the examiner is not persuaded by Declarant's current stance, that the subject matter of the claims of Goldman et al ('084) is inoperable."

Continuing, appellant asserts that Goldman et al ('084) is not enabled for the use of lasers, because there is no disclosure regarding laser wavelengths or power levels. Interestingly, the disclosure with respect to the RF embodiment, there is also not disclosure with respect to wavelength or power level or duration of energy application. Yet somehow one of ordinary skill in the art would be enabled to make and use the invention with respect to this modality, but unable to do so with the laser embodiment, despite the fact that other practitioners in the art (e.g. C. Boné mentioned above) were using laser radiation to treat varices at the time of the invention of Goldman et al ('084). This argument is simply not credible, given the familiarity of one of ordinary skill in the art with the application of laser wavelengths in the claimed range to tissue, particularly blood vessel tissue, as evidenced by Dew et al and Sinofsky. Ironically, appellant points to Sinofsky to show the "type of laser, the laser wavelength, the power levels and dose duration" (see the instant Brief, page 16, last sentence) for affecting the vascular tissue, ignoring the fact that Sinofsky is not only part of the prior art with which one of ordinary skill in the art

would be familiar, but also the fact that Sinofsky has been used in rejecting the claims. In view of this knowledge in the prior art, it is not clear how appellant can assert the one of ordinary skill in the art is "left entirely in the dark" (see the instant Brief, page 16, last full paragraph, first sentence) with respect to the laser wavelengths available and their effect on th4e chromophores involved in treating blood vessels.

Then appellant once again makes reference to Navarro, asserting (in a footnote on page 17 of the instant Brief), that the examiner "has steadfastly and mysteriously refused to rely on the Navarro patent as a reference". As set forth in the Final Rejection, mailed March 13, 2009:

> The examiner will note here that Appellants have devoted a portion of the Brief to discussion of the Navarro Patent, which has not been applied to the claims by the examiner. This "second guessing" of the rejection which, in appellants' opinion, the examiner should have applied to the claims is noted, however, is of little moment with regard to the analysis of the rejections which actually have been applied to the claims, and will not be discussed further herein. The fact is that the examiner considers the applied references as combined in the

rejections set forth to constitute a *prima facie* case of obviousness. If appellant believes that the Navarro patent in combination with other prior art references to constitute a superior showing of a *prima facie* case of obviousness over the applied reference, appellant is respectfully urged to bring these combinations to the attention of the examiner and fully explain how this combination would read on the claims at bar, that the examiner many fully evaluate this showing. Absent this, in the examiner's opinion, the applied combination is sufficient to establish the case official notice of which is hereby taken, *prima facie* obviousness, and other reference combinations need not be applied.

Even though the primary embodiment of Goldman et al is related to RF, rather than laser, application to provide the desired treatment, the process Goldman et al wish to implement is

clearly set forth: the method is aimed at either completely closing off (see column 2, lines 41-50) or greatly reducing, while still allowing to remain patent (see column 2, lines 51-65) the vein, or other anatomical tubular structure to be operated on; the vein is treated by applying energy to the vein wall, to shrink it (see Goldman et al column 5, lines 58-65), which energy, being applied to the vein wall, heats it and causes it to shrink (see Goldman et al column 9, lines 5-13 and column 13, lines 14-24); the device can then be pulled back to treat further portions of the vein (column 13, lines 15-30). The principles of the method having been disclosed to one of ordinary skill in the art, if it were desired to employ the laser embodiment of Goldman et al, one of ordinary skill in the art would, of necessity, look to the art of laser treatment to determine the appropriate parameters which would be required to fulfill the principles set forth in Goldman et al, e.g. providing energy to the vein wall to heat it and cause it to either shrink, or be completely occluded. Sinofsky teaches a laser device to remove plaque from blood vessels or repair defects in small diameter artery walls (see column 1, lines 36-37) and for material removal and biological material repair (see column 2, lines 50-52), which repair can be effected by coagulation (see column 3, lines 25-28), which preferred laser wavelengths are in the range of approximately 1.4 to 2.2 microns and can be transmitted through blood (see column 4, line 47 to column 5, line 6). Sinofsky also teaches that one of ordinary skill in the art is familiar with the various calculations necessary to determine the appropriate parameters for providing a given amount of heat to the tissue being acted on (see column 10, line 50 to column 11, line 41, and appellant's comments at page 16, the last sentence of the instant Brief), while these are couched in terms of the primary embodiment of vaporizing plaque, the equations could also be used to calculate the amount of heat necessary to provide tissue repair e.g. by coagulation of the tissue,

as disclosed in a secondary embodiment of Sinofsky. Dew et al teaches that the extent to which tissue is heated by laser energy is dependant upon the extent to which the energy is absorbed by the tissue and notes that wavelengths that pass through blood relatively unattenuated, such as the 1.32 micron wavelength, are useful (see column 5, lines 47-65), which coincides with Sinofsky's range of **approximately** 1.4-2.15 microns (see column 4, line 49 of Sinofsky). Thus, clearly, the teachings of Goldman et al, taken with the knowledge of one of ordinary skill in the art, the use of the teachings of Dew et al and Sinofsky merely constitutes a predictable use of prior art elements according to their established functions (see KSR International Co. v Teleflex Inc. 82 USPQ2d 1385, 1396 (Supreme Court, 2007)) . As such, appellant's arguments that Sinofsky and Dew et al cannot be combined with the teachings of Goldman et al ('084) are not well founded.

Continuing, appellant asserts that, with regard to the motivation stated by the examiner for the combination of the applied references to "state this proposition is to refute it", further asserting that this "demonstrates a very serious lack of reasoning and has no rational underpinning" (see the instant Brief, page 19, first and second full sentences). The examiner must respectfully disagree. The explicit rationale set forth in the rejection is sound, and remains unrebutted by any facts set forth by appellant, who has chosen to instead deride the examiner for holding his position, and continually raise the red herring of the Navarro reference, which the examiner has never applied to the claims. Interestingly, appellant has chosen to avoid addressing the fact that even if Goldman et al ('084) is not enabled for the use of lasers as of the filing or issue date of the Goldman et al ('084) reference, the real issue is whether the disclosure of Goldman et al ('084) in combination with the prior art and knowledge of one of ordinary skill in

the art would have enabled the use of lasers as of the filing date of the instant application, which is October 30, 2003, well after the publication of all the laser applicators mentioned in the publications attached as Appendix 2 to the instant Brief. This is the standard upon which the *prima facie* case of obviousness is based for any patent application, one which appellant has chosen to ignore.

Next appellant makes reference to Board Decisions wherein the examiner has not provided sufficient reasons for the combination of references, however, as the examiner has made a reasoned statement for the combination of the references applied to the claims, the holdings referenced are not applicable to the instant rejections.

Lastly, with regard to the enablement of Goldman et al ('084), it is interesting to note that despite the assertions of non-operability for laser energy, the assignee of Goldman et al ('084), rather than file for a ReIssue application correcting a patent that claims more than the inventors had a right to claim, instead chose to use the patent to sue competitors producing laser systems for treating varicose veins:

> On July 21, 2005, a lawsuit was filed against us in the United States District Court for the Northern District of California by VNUS Medical Technologies, Inc., alleging infringement of **U.S. patents Nos. 6,258,084**, 6,638,273, 6,752,803, and 6,769,433. The complaint was served on us on July 27, 2005. On September 15, 2005, we filed an answer denying the allegations of infringement, and counterclaiming against VNUS for a declaration that none of the patents are infringed and that they are all invalid. (emphasis added)
> See the Annual Report of Diomed Holdings March 20, 2007. This is strong

evidence of operability of Goldman et al ('084).

b) The teachings of the secondary references

As the teachings of the secondary references are properly combined with Goldman et al, both because they are from the laser surgery field, which Goldman et al points to by discussing lasers, and because they deal with the removal or repair of tissue in tubular organs, which Goldman et al teach, without limitation to blood vessels per se, the fact that they do not explicitly teach the treatment of varicose veins is not a bar to their combination with Goldman et al.

c) The examiner has given due consideration to the evidence submitted by appellants

Appellants assert that the examiner has "refused to consider" the evidence proffered to establish non-obviousness. The examiner must respectfully disagree. The examiner must first point out that the contents and teachings of the articles were analyzed in the rejection mailed May 17, 2006 in the paragraph bridging pages 2 and 3 thereof. However, appellants have neglected to discuss this treatment of the submissions, instead preferring to focus on the examiner's comment in the subsequent rejection, the final rejection mailed February 12, 2007.

It is important to note that the articles and product information were submitted with Affidavits and that all Affidavits only aver that the submissions are "true copies" of the articles or product literature which is described in the Affidavits. There is no assertion whatsoever in any Affidavit of record that the articles or product literature are in any way representative of the prior art with respect to varicose vein treatment. Instead such assertions are made only in the remarks accompanying the affidavits. This is interesting, given that these remarks bear the signature of Mr. Geriak, one of the affiants. However, as these assertions are only submitted in the form of remarks accompanying a response, they cannot be elevated to the status of evidence.

As such, these remarks are noted, but do not speak to the propriety of the combination which the examiner has applied to the claims.

Further, the issue at hand, with respect to the rejection under 35 U.S.C. 103(a) involving Goldman et al ('084) is not whether the inventive entity of Goldman et al ('084) were using lasers at the time that application was filed, nor whether Navarro et al used, envisioned using, or intended to use laser wavelengths in the claimed range, 35 U.S.C. 103(a) states, in pertinent part "a patent may not be obtained…if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious **at the time the invention was made** to a person having ordinary skill in the art…" (emphasis added). Thus, given the fact that the time at which the invention of Navarro et al was made (e.g. the filing date thereof August 13, 1999) and the time at which the invention of Goldman et al ('084) (again, e.g. the filing date thereof March 10, 1999) are both several years before the instant effective filing date (October 31, 2003). Thus any lack of obviousness that can be established for individuals in the late 1990s does not necessarily reflect a lack of obviousness for individuals in the latter half of 2003. Thus, Declarant's and appellant's statements are insufficient to show a lack of obviousness at the time the instant invention was made.

I) Rejection Of Claims 1, 2, 6, 7, 25, 35-38, 40, 41, and 44-46 Are Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over Goldman et al ('084) in combination with Sinofsky and Dew et al

As set forth above under a), the prior art is properly combinable and properly combined so as to establish a *prima facie* case of obviousness. Appellants characterize the disclosure of the use of a laser to heat the blood vessel wall as "no more than a throw away mention of lasers".

However, this is clearly not the case. The use of a laser is clearly set forth as an equivalent alternative to the RF method more thoroughly described, as well as the resistive, microwave, ultrasound, and other types of tissue heating devices set forth in Column 7 of Goldman et al. It is a well understood point of law that "All of the disclosures in a reference must be evaluated for what they would fairly teach one of ordinary skill in the art. Thus in [citations omitted] this court affirmed rejections based on art which we concluded rendered the claimed invention obvious to those of ordinary skill in the art despite the fact that the art teachings relied upon in all three cases were phrased in terms of a non-preferred embodiment..." (see In re Boe 148 USPQ 507).

II) Claims 3-5, 42, And 43 Are Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over Goldman et al ('084) in combination with Sinofsky Dew et al and Roth et al

With regard to this rejection, appellants merely assert that the additional reference does not overcome the deficiencies of the base rejection. Asserting that the teachings of Roth are set forth "in an entirely different context" (see the instant Brief, page 20, last full paragraph, second sentence). However, Roth is related to laser treatment of hollow organs, as disclosed and claimed by Goldman et al ('084), thus it is unclear on what basis appellant is asserting that this reference is in an entirely different context, especially since Goldman et al ('084) specifically recite a pull back device. Thus the base rejection is not deficient, this argument is not convincing.

III) Claims 8 and 39 Are Obvious Over Goldman et al ('084) in combination with Sinofsky Dew et al and Conn et al

With regard to this rejection, appellants merely assert that the examiner has not provided a rational underpinning for the use of a diffuser. However, the examiner has specifically stated

that the use of the diffuser of Conn et al "would provide a uniform distribution of light and would prevent over or under treatment of tissue different areas of tissue (see page 2, first full paragraph)" (see the Final Rejection, page, 26, first full paragraph, last sentence), which is considered a proper "rational underpoinning under the guidance set forth in KSR International Co. v Teleflex Inc. 82 USPQ2d 1385 (Supreme Court, 2007). Thus this argument is not convincing.

IV) Claims 9-13 Are Obvious Over Goldman et al ('084) in combination with Sinofsky Dew et al and Makower et al

With regard to this rejection, appellants merely assert that the additional reference does not overcome the deficiencies of the base rejection. However, as Goldman et al ('084) specifically teach providing temperature sensors at the site (Abstract, last sentence), it is unclear how the teachings of Makower et al are not applicable thereto.

V) Claims 14-17 And 20-23 Are Obvious Over Makower et al in Combination With Roth et al, and Dew et al

With regard to the combination involving Makower et al Roth et al and Dew et al, appellants argue that none of the reference deal with the intended use of the device. The examiner respectfully notes that to render an apparatus claim obvious, it is merely necessary that the examiner provide a *prima facie* case of obviousness for the structure claimed, not the method envisioned by appellants. As set forth above, Makower et al teach a device including an introducer, an optical fiber and a means that can be used to administer anesthetic. Since Makower et al provide no wavelength information, one of ordinary skill in the art would be motivated to employ the versatile laser of Dew et al, which could nto only provide the main

wavelength suggested by Roth et al, but also the 1.32 micron wavelength that could be used to seal the holes discussed in the first full paragraph of page 16 of Makower et al, which would further reduce the chance of infection therefrom.

Appellants also postulate that a pull back mechanism is incompatible with the Makower device, which includes a locking mechanism. However, a careful reading of the Makower et al reference reveals that the locking mechanism only locks the cannula, as can be seen by the disclosure that the fiber can be completely removed and reinserted while the cannula is locked in place (see Makower et al, page 20, first full paragraph), thus no incompatibility exists, and the pull back device would allow for the treatment of a length of the prostate without removing and re-situating the cannula. Thus this argument is not convincing

VI) Claim 19 Is Obvious Over Makower et al in Combination With Roth et al, Dew et al, and Conn et al

With regard to this combination, appellants have argued that none of the references of the base combination call for a diffuser. However, since one of the many embodiments of Makower et al involves photodynamic therapy (see Makower et al, page 20, second sentence) and the diffuser of Conn et al may be employed for photodynamic therapy, (see page 1, the first sentence under "BACKGROUND AND SUMMARY OF THE INVENTION") this argument is not convincing.

The examiner will note here that Appellants have devoted a portion of the Brief to discussion of the Navarro Patent, which has not been applied to the claims by the examiner. This "second guessing" of the rejection which, in appellants' opinion, the examiner should have applied to the claims is noted, however, is of little moment with regard to the analysis of the

rejections which actually have been applied to the claims, and will not be discussed further herein.

Then appellant asserts that prior to the present invention "all of the laser devices for patient treatment of varicose veins used lasers having wavelengths in the range of 810-980 nm". The examiner finds this assertion curious in light of the teachings of Navarro et al, touted by appellant as the first use of lasers with wavelengths of 500-1100 nm to treat varicose veins. Clearly wavelengths outside the narrow range of 810-980 nm were already contemplated by one of ordinary skill in the art. This also ignores the specific teaching of Goldman et al ('084) of heating the vessel wall to cause it to assume compressed dimensions, i.e. shrink (see Abstract, fifth and sixth sentences). Additionally, it has nowhere been established that "**all** of the laser devices for patient treatment of varicose veins used lasers having wavelengths in the range of 810-980 nm" (emphasis added) as there is no evidentiary showing that appellant has not provided data for **all** devices that have ever been used

Next appellant asserts that at the time of the invention "it was the prevailing scientific view that the use of laser wavelengths above 1064 was undesirable" (see the instant Brief, page 25, first full paragraph, first sentence). This is interesting in view of appellant's touting of the Navarro reference, which specifically calls for the use of 1100 nm, which is greater than 1064 nm. The basis for this is the assertion that these wavelengths are necessary for hemoglobin to be the chromophore (see the instant Brief, page 25, first full paragraph, second sentence). However, the use of hemoglobin as the chromophore is immaterial in view of the specific call by Goldman et al ('084) to use constituents of the vessel wall as chromophores (see Goldman et al ('084) Abstract, fifth and sixth sentences). Thus calls by

various authors of the articles and/or patents referred to in the arguments to use other chromophores are immaterial in view of the explicit disclosure by the base reference of the combination (i.e. Goldman et al ('084)) to use the vessel wall as the absorbing body (i.e. the chromophore).

With regard to the teachings derived from the publications submitted by appellant, appellant asserts that the examiner "seems to abandon the position" that:

> Applicant then posits that in the real world those attempting to use lasers "to accomplish the purpose of Goldman" deliberately chose not to use applicant's wavelengths. The examiner must respectfully disagree. Firstly, it is noted that the three articles submitted by applicant's do not constitute a statistically significant sample of all the publications dealing with laser treatment of varicose veins and as such cannot be the basis for a claim such as made by applicant. Secondly, the "purpose of Goldman" is to heat the vessel wall (see, for example column 9, line 13). The purposes of the articles submitted by applicant is to heat the blood in the vessel. And, as clearly taught by Dew et al and set forth above, this is achieved by employing wavelengths that are absorbed by the tissue that is desired to be heated.

The examiner has not done so, regardless of the teachings of the publications submitted by appellant, the fact remains that the teachings of the base reference used in the rejections of the method claims include the express statement that the desired target of the energy applied to the varicose veins is the vessel wall. No amount of argument on the part of appellant or statements in affidavits can erase this express teaching from the Goldman et al ('084) reference. It remains irrevocably part of the teachings of the prior art of treating varicose veins.

With regard to the statement at paragraph 10 of the Hennings Declaration, wherein Declarant states that the examiner was "incorrect in refusing, at page 11 of the Examiner's answer, to accept the assertions of our counsel, Mr. Geriak, that Exhibits A, B, and C to his declaration

were representative of the prior art", this statement is interesting for several reasons. Firstly, Declarant never expressly states that it is Declarant's belief that these articles are representative. Secondly, Declarant merely states that the examiner erred in not accepting the arguments (proffered only in the comments, and not in the Declaration that Mr. Geriak himself authored, which was submitted on even date with the arguments).

With regard to the statement at paragraph 8 of the Goldman Declaration, wherein Declarant states that the use of the claimed wavelength range was "undesirable". However, there is no negative statement whatsoever in any of the submitted articles with respect to the undesirability of any wavelength range. Thus the examiner is at a loss to regard this statement as evidence as it is in direct conflict with the facts. The mere act of using one wavelength is not an indictment of using all other wavelengths. The fact that the articles report success with the wavelengths employed does not correlate to other wavelengths being unsuccessful or taught away from, otherwise one could assert that the 810 nm wavelength taught by Min et al was taught away from by Proebstle et al by their use of the 940 nm wavelength. Drawing such a conclusion from this set of facts is a logical fallacy. If one is hungry when it is noon, one cannot then determine that it must be noon whenever one is hungry. Similarly, if one wavelength is used successfully for treating varicose veins, one cannot assume that if other wavelengths are used, the treatment will be unsuccessful..

(11) Related Proceedings Appendix

NONE

(12) Conclusion

It is the examiner's firm opinion that the appealed claims are not patentable for the reasons argued above. Appellant has presented no convincing argument as to why the rejections set forth above are not obvious or proper. Therefore, it is respectfully submitted that the final rejection be affirmed.

Respectfully submitted,

/david shay/

Primary Examiner, Art Unit 3769

David Shay
November 6, 2008

Conferees
/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

/Greg Vidovich/
TQAS, TC 3700

OPRICK, HERRINTON & SUTCLIFFE LLP
4 PARK PLAZA, SUITE 1600
IRVINE, CA 92614-2558